



LEGAL PROVIDING PROBLEMS IN USING THE NEWEST TECHNOLOGIES

Trynova Yana - PhD, Associate Professor, lawyer

Представленная статья посвящена одному из направлений новейших технологий – нанотехнологии: ее концепции и масштабам использования. Особенно в статье акцентируется внимание на негативных аспектах этого явления. Указывается на пробелы в различных отраслях украинского законодательства в отношении установления безопасного использования нанотехнологий. Отсутствие надлежащего законодательного обеспечения этой отрасли представляет реальную угрозу существования всей экосистемы, частью которой является человечество. В статье задан вектор последующих возможных исследований в области комплексной правовой поддержки нанотехнологий.

Ключевые слова: новейшие технологии, нанотехнологии, наночастицы, биоэтика, биотехнология, правовое обеспечение

This article focuses on one type of newest technology - nanotechnology. A concept of nanotechnology and the scope of their use. Feature article is parting the emphasis on the negative aspects of this innovation. Points to the gaps in the various branches of the Ukrainian law with regard to the establishment of the safe use of nanotechnology. Such state laws pose a real threat to the disappearance of all ecosystem, part of which is the people. The article given a vector followed by research in the field of integrated legal support nanotechnology.

Keywords: newest technology, nanotechnology, nanoparticles, bioethics, biotechnology, legal providing.

Acest articol este dedicat orientării către tehnologiile moderne - nanotehnologia: concepții și domenii de aplicare. În special, în acest articol se pune accentul pe aspectele negative ale acestui fenomen. Sunt evidențiate probleme din diferite sectoare ale legislației ucrainene, privind stabilirea siguranței în utilizarea nanotehnologiei. Lipsa unui sprijin legislativ adecvat de siguranță a acestei ramuri prezintă o amenințare reală pentru existența întregului ecosistem, parte a căruia este și omenirea. În acest articol a fost stabilit vectorul de cercetări de perspectivă posibile în sprijinul juridic complex în domeniul nanotehnologiei. Cuvinte cheie: tehnologii moderne, nanotehnologie, nanoparticule, bioetica, biotehnologie, suport legal.

Formulation of the problem. One of the results of unrestrained development of scientific and technological progress is the development and use of nanotechnology. However, despite the intensive development this industry, today completely absent legislative means of its control.

Condition of the problem elaboration. Unfortunately, among the Ukrainian legal publication with suggestions for regulatory support this industry, we have not met.

The aim of the article is to focus on the lack of Ukrainian legal support in the field of nanotechnology. Outlining a circle of nanotechnology, the

consequences of their use and focusing on gaps in legislation, this article sets the vector further scientific developments in the field of regulatory support nanotechnology methods of state regulation.

Statement of the base material. At present the latest trends of scientific and technical and technological progress are not the only means of solving the urgent needs of mankind, but also become a factor in the emergence of new threats and risks. If the second half of the twentieth century, these risks and dangers arise due to the rapid development and wide application of a wide range of chemical compounds, nuclear energy and electronics industries, and later genetically modified organisms at the beginning of the XXI century more and more attention is paid to issues related to the development and application of compounds, materials and devices based on nanomaterials and nanotechnologies.

The term "nanotechnology" refers to a set of methods and techniques, enabling a controlled manner to create and modify objects, including components with sizes less than 100 nm, having a fundamentally new quality and allows for their integration into a fully functioning macroscale systems. Almost nano (from the Greek Nanos - Dwarf) - a billionth of something, nanometer - a meter, divided into one billion [1]. To visually you can imagine the scale of nanotechnology objects can be compared to a tennis ball and the planet - is such a difference between the ordinary and nanotechnology device.

Prospective application of nanotechnology implementation results are the determining factor in the configuration of political and moral future.

At the same time, an extremely important role in the development of society, begins to play the ethics of science itself and the fruits of scientific research, especially in the area of nanobiotechnology, matching the results of the study morality, strategic steps and development of standards in order to achieve the final (both intermediate) goal - a quality coexistence of mankind together with the natural environment of its habitat and the biosphere as a whole. Nanotechnology, and associated knowledge, go out on the front flank of the scientific and technical progress, it is promising in the foreseeable future to become one of the leading areas of world science and economics. Today nan-

otechnology are used in various fields of industry, medicine, information and telecommunications, as well as in the areas of conservation of materials and energy, improving detection methods and overcome the consequences of environmental pollution, etc. [2].

The social implications of nanotechnology development are bivalent character. The specificity of the dual nature of the development of nanotechnology lies in the cardinal transformation of the physical world, and it takes account of possible irreversible effects [3, p.75 -76].

Thanks to huge advances in science and technology, mankind has at its disposal unprecedented powerful tools that can be used both for creation and for destruction, for good and harm. Therefore, in the XXI century the problem of assessing these phenomena through the prism of moral and ethical values is of particular importance.

Scientists the world claim that the introduction of nanotechnology and nanobiotechnology in different sectors of the economy, including a computer and microwave technology, solar panels, radio, radiology, molecular biology, medicine, pharmacology, pharmacy, veterinary medicine, environmental monitoring, creation nanodevices, in the defense industry (the development of protective vests, special weapons control systems, etc.) will be a kind of nano revolution of the XXI century, and its consequences will be more decisive than the development of nuclear energy and space, computerization of human activity, the development of the Internet system in the second half twentieth century. Today found that with decreasing particle size of from 10 to 100 nanometers are relatively weak and range from 10 nanometers to 1 - drastic changes of physical and chemical properties of materials, in particular metals. Changing parameters of the crystal lattice, the melting point, the electronic structure of the crystal, and other properties [3, 76].

The small size of metal nanoparticles means that the majority of the atoms are on the surface, and thus the behavior of surface atoms changes their chemical, physical, physico-chemical, biological and pharmacological properties. Nanoparticles can more easily penetrate the human body and to be more biologically active due to their large surface area per unit weight, compared with Mac-

rodimension particles. Nanobiotechnology create conditions for obtaining substances of different chemical nature, which exhibit a pronounced pharmacological effect. Small size, chemical composition, structure, large surface area and shape - are those properties that the nanoparticles provide an advantage over other materials, and simultaneously provide their potential toxic effects on biological systems.

The large relative area (per unit mass) nanomaterials greatly increases their adsorption capacity, chemical reactivity and catalytic properties. High adsorption of nanoparticles and nano activity characterized by the ability to adsorb per unit mass more compounds and chemicals, as compared with macroscopic dispersions. This property must be considered of nanoparticles, as they can adsorb on the surface of toxic chemicals and to facilitate their transport to the cells, substantially increasing the toxic properties of the latter.

Nanoparticles due to their small size poorly recognized by protective systems of the body, and as a consequence, do not undergo biotransformation and excreted from the body, which contributes to their high biological media accumulation in the body [3, 81].

Researchers in this field V. Dyachenko and T. Nebesnaya argue that the most sensitive to nanoparticles are the bodies which directly interact with the environment, - the respiratory system, gastrointestinal tract, skin, and blood and central nervous system. Furthermore, it was found that nanoparticles may cause a direct cytotoxic effect on endothelial cells in vitro Human umbilical vein. Currently, direct studies on the toxic effects of nanobiotechnology products on the human body is small. A particularly important aspect of the study of toxicology of nanoparticles is to assess the potential long-term effects nanobioproducts [4, 76].

As noted by their colleagues from the State Institution "Institute of Occupational Medicine of Medical Sciences Academy of Ukraine", modern toxicological and epidemiological studies have shown the benefit of that cause changes in the state employees' health may be ultrafine particles entering the body by inhalation. In particular, even a short-term impact of nano particles present in the air of the working area can cause different re-

actions on the part of the cardiovascular system (from minor cardiac arrhythmias to myocardial infarction and thrombotic) and respiratory tract (impaired lung clearance, chronic inflammatory processes, fibrosis of the lung tissue and lung cancer). In turn, today decided to establish a diagnosis of cancer pathology on the basis of X-ray data, ultrasound data, computed tomography, etc., which, in fact, allow the identification of the disease already. Consequently, for the purposes of medical prevention of cancer pathology, these methods are not very suitable, because although aimed at the earliest, but the detection of already established tumors. Due to the fact that the potential cancer risk due to exposure to dangerous carcinogenic environment factors, cannot be realized for all workers, it is extremely important to identify individuals who are most susceptible to the development of malignant tumors. Therefore, it is important to use methods to identify pre-clinical manifestations of malignant neoplasms in the working population. Thus, it is advisable to provide working in the field of nanotechnology allow passage with a certain frequency of laboratory tests to identify tumor markers. Of course, the consent of the employee must be completely voluntary and be solely the result of personal choice based on full information about the situation. In the case of a positive reaction in onkoteste, the employee has a number of possibilities to go in-depth survey, go to a different, more secure portion of the production process or even negligible results onkotesta. On the other hand, in the case of conscientious worker to undergo tests preclinical diagnosis of cancer pathology, a number of issues of so-called ethical and practical. For example, if in the future the employee will be found a cancer - it ethical to raise the issue of compensation. Conversely, there is an ethical refusal to reimburse the owner of the enterprise, organization or institution harm caused to the employee when he deliberately refused to undergo onkotest? [5, p.79 -80]. The truth in this case, you can connect the institute of mediation, which is widely used abroad.

The widespread adoption of nanotechnologies and nanomaterials in production and daily life without a thorough fundamental and toxicological-hygienic and environmental research is a concern about the safety of their use and of

possible threats to public health and the environment. According to V. Demetskaya, T. Tkachenko and A. Leonenko according to their survey, only about 10% of workers in research laboratories and about 20% of the employees of organizations that specialize in working with nanomaterials, familiar with the handling and disposal of nanomaterials rules. The third part of the respondents, or general laboratory uses individual means of protection to prevent the ingress of nanoparticles in the body [6] (- Ya.T.). These results can be called breathtaking and the degree of danger to health with research scientists compared the radioactivity in the early twentieth century.

The situation in the production of nanomaterials on the market requires solutions. In terms of production and laboratory work should be carried out with appropriate safeguards for workers and the environment. Consumers nanoproducts properly should be aware of the potential risks. Necessary to develop monitoring systems, methods and monitoring devices and detection nanosubstances in the environment, and improving the mechanisms of their toxicological and hygienic assessment. At present, the problem requires solving the waste regulation of emissions enterprises and nanotechnology industry, as well as assessment of the life cycle of nanomaterials in the environment. When the regulation of nanomaterials and nanosubstances necessary to observe the principle of safety in use and its advantages over commercial benefit from the introduction of nanomaterials, as well as strict control of the state.

As it noted, despite the rapid development of nanotechnology. Not only the workers, employers and citizens, but even a significant percentage of the researchers are not aware of the potential risks associated with exposure to nanomaterials. This is a problem not only for Ukraine but also for Europe and the United States. According to the State Workers' Institute for Occupational Medicine of Medical Sciences Academy of Ukraine "A. Demetskoy, T. Tkachenko and A. Leonenko, even in the developed world, there is no register of companies using nanotechnology. However, in contrast to Ukraine, the USA and the EU countries do certain steps to ensure the appointment nanosafety. In particular, the Organization for Economic Cooperation and Development (OECD) addressed to

employers with a request to provide information to account for businesses and workers with occupational exposure to nanomaterials. In turn, the US National Institutes of Occupational Safety and Health (NIOSH) distributes benefits to employers, employees and occupational health specialists, which contain in an accessible form the information about the features of the biological effect of nanoparticles, routes of their body, personal protective equipment and capabilities risk management in the production of [7, p.65].

In contrast to the Ukrainian employers, trade unions and European colleagues who adhere to good manufacturing practices, concerned about the possible negative impact of nanoparticles on the body of employees. This concern is the practical expression. In their insistence carried out to monitor the exposure of nanomaterials and set at least temporary calculated hygienic standards. Today the regulation of nanomaterials is associated with certain constraints, so the acceptable number nanoparticles / nanomaterials in the working area are not defined either in Ukraine or in other countries. As a result, A. Demetskaya, T. Tkachenko and A. Leonenko, while British Standard BSiPD 6699-2: 2007 provides a practical approach and proposes to use the so-called "reference exposure levels" (Benchmark exposure level) in order to achieve reasonable levels of safety of nanomaterials [7, p.65]. However, these levels do not guarantee the same security, the acceptable number for working zone air, established by experimental studies.

As a guideline for the safe concentration limit calculation of nanoparticles in the working area in the application of nanotechnology, Ukrainian scientists can take the standards proposed by the Institute of Occupational Safety and Health of Germany and the United States (IFA and NIOSH) [8]. These standards can become a reference point for national scientists in the development of standards for the admissibility of the concentration of nanoparticles in the air. On this basis, the legislator can create regulatory support in this area.

According to the Belarusian bioethics researcher T. Mishatkina, nanotechnology became the basis for a new direction - nanoethics. The researcher leading principles on which, in her opinion, should be developed nanotechnology in

biomedicine [9, p.97]. By the way, these principles correspond to the principles developed by us - axiological bioethics principles, which have been published in other studies [10, s.161-163].

The similarity in the wording of the principles of bioethics is quite justified, because these principles are trying to develop a lot of bioethics scholars. The objective of the legislator - to choose from all the offers provided by the best by modern scientists, and to implement them in national law. It is for this and there is a science in all its forms: doctoral research, scientific papers, round tables, conferences, etc.

Currently, there are numerous questions about the ethical use of the achievements of nanomedicine, in particular, the issue of informed consent, risk assessment; human toxicity. Discussion of the ethics of nanomedicine and contains many difficult problems for society. In fact, nanomedicine raises many social issues. So, it is very difficult when using nanomedicine, is the issue of informed consent. Although the patient's consent to receive possible and it is not too difficult, but it is unknown when the patient is able to receive a full and independent information. Informed consent implies that the information is understandable. However, is it possible to provide information on the impact of research that develop quickly, and implement a realistic risk assessment, given the many unknown factors and complexity? At the conclusion of domestic experts, due to lack of knowledge and the complexity of the issue it will be difficult to provide adequate information about the proposed diagnosis, prevention and treatment, which will be required to obtain informed consent.

Another problem - associated with the use of medical and non-medical fields of nanotechnology for diagnostic, therapeutic and preventive purposes. It remains an open question, whether to use nanotechnology to make deliberate changes in the body, when changes are necessary not from a medical point of view. Despite the huge potential and the significant financing of nanomedicine, the study of the ethical, legal and social implications, applications of this field is still insufficient. We fully share the view of the domestic medical scientists V. Korolenko, P. Muzychenko and A. Rybachuk that the problem of the danger of nano-medicine will exist as long as the study of the ethical, legal

and social implications behind the scientific development [11, p.82].

To summarize laid down. According to projected estimates, in the coming years is the development of nanotechnology will be one of the main factors to stimulate major changes in the industry, agriculture and medicine. At the same time, and it should be noted that nanotoxicology specialists and experts of leading international organizations insist that characterize nanotechnology as "business as usual", we ignore the lessons of the past and are exposed to a double risk. So, on the one hand, the risk of severe exposure industrial nanoparticles on human health and the environment. On the other hand, in case of failure of nanotechnology, we refuse to acquire new knowledge and potentially beneficial developments in various spheres of life.

Today we can talk about nanosafety - the impact of nanotechnology on the environment and life safety. In general, the range of nanosafety problems using nanotechnology can be defined as follows: occupational safety, consumer health and environmental protection. Today, there are the following aspects in the field of safety of nanotechnology and nanomaterials: biomedical (research of features of the biological effect of nanoparticles, toxicity parameters, effects on health and the environment), legal (legislative support nanotechnology), and ethical.

Regarding the ethical aspects nanosafety. Firstly, we are talking about raising themselves the product manufacturer in the industry, working in her individual and the population in general about the use of nanotechnology and the potential danger of nano particles. Secondly, it is necessary to take into account the possible impact of nanotechnology on the environment. Today in the world in general and in Ukraine in particular, actively emerging market nanoproducts nanoserves and therefore an important aspect is to provide the most complete and adequate information, as public awareness in this area is extremely insufficient. According to the testimony of A. Demetskoy certain part of citizens enthusiastically accepts the prefix "nano" in front of any goods and services, while others categorically refuse the use nanoproducts because of fears of a negative impact on their health, and, finally, a certain percentage of

people do not care, they do not understand what question.

Legal regulation of the industry in Ukraine is not yet available, which creates a great danger to human health and life. Adopted in recent years, "The Code of Ethics of the scientist of Ukraine" and "Code of Ethics of the doctor of Ukraine" declare a common standard that can be applied in nanoscience, but it must be taken into account and the specific features of this sector. Right system construction to bioethical principles provides for a review of a number of legal acts to the new opportunities of medical and biological sciences and their relation to human rights and environmental safety conditions in the aspect of the development of nanotechnology and nanomedicine. Therefore, to effectively address the legal and ethical aspects of nanotechnology appropriate legal framework should be created, which will be presented in my future publications.

References

1. Нанотехнологии. Что это <http://www.nanosvit.com/index/0-5>
2. M.C. DeRosa, C. Monreal ets. Nanotechnology in fertilizers // *Nature Nanotechnology* May 2010, Volume 5 No 5, p.91 (2010) <http://www.nature.com>
3. Смалько П.Я., Стехіна Т.Ю., Скребцова К.В., Чащин М.О. Нанотехнології та сучасне суспільство // 4 нац. конгрес з біоетики з м/н участю 20-23.09.10, м. Київ: Збірник тез доповідей / Упор. к.ю.н. Гревцова Р.Ю. – Київ: Видавництво «КІМ», 2010. – 235с. с.75-76
4. Дяченко В.Ю., Небесна Т.Ю. Нанобіотехнології: соціально-етичні аспекти // 4 нац. конгрес з біоетики з м/н участю 20-23.09.10, м. Київ: Збірник тез доповідей / Упор. к.ю.н. Гревцова Р.Ю. – Київ: Видавництво «КІМ», 2010. – 235с.
5. Трахтенберг І.М., Апихтіна О.Л., Дмитруха Н.М. Етичні аспекти впровадження наноматеріалів // 4 нац. конгрес з біоетики з м/н участю 20-23.09.10, м. Київ: Збірник тез доповідей / Упор. к.ю.н. Гревцова Р.Ю. – Київ: Видавництво «КІМ», 2010. – 235с.
6. Демецька О.В., Кучерук Т.К., Мовчан В.О., Рибак О.О. Проблеми інформованої згоди та доклінічної діагностики працюючих у сфері нанотехнологій // 4 нац. конгрес з біоетики з м/н участю 20-23.09.10, м. Київ: Збірник тез доповідей / Упор. к.ю.н. Гревцова Р.Ю. – Київ: Видавництво «КІМ», 2010. – 235с.
7. Демецька О.В., Ткаченко Т.Ю., Леоненко О.Б. Етичні та нормативно-правові аспекти використання нанотехнологій // 4 нац. конгрес з біоетики з м/н участю 20-23.09.10, м. Київ: Збірник тез доповідей / Упор. к.ю.н. Гревцова Р.Ю. – Київ: Видавництво «КІМ», 2010. – 235с.
8. Nanotechnology in Germany and USA // "Nature Nanotechnology", December 2011, Volume 6 No 12 p.755-760 <http://www.nature.com>
9. Мишаткина Т.В. Нанозтика в биомедицине: проблемы биобезопасности // Міжнародний (Третій Всеукраїнський) конгрес з медичного і фармацевтичного права, білетики та соціальної політики 19-21 квітня 2012 року, м. Київ: Збірник тез доповідей / Упор. д-р О.Асман, к.ю.н. Гревцова Р.Ю., д.м.н. Степаненко А.В. – Київ: Видавництво «КІМ», 2012 – 156с.
10. Триньова Я.О. Біоетичні засади кримінально-правової політики в Україні // Політика в сфері боротьби зі злочинністю: Матеріали Всеукраїнської науково-практичної конференції. – Івано-Франківськ: Прикарпатський національний університет імені Василя Стефаника, 2013. – 307с.
11. Короленко В.В., Музиченко П.Ф., Рибачук А.В. Проблеми біоетики в наномедицині // 4 нац. конгрес з біоетики з м/н участю 20-23.09.10, м. Київ: Збірник тез доповідей / Упор. к.ю.н. Гревцова Р.Ю. – Київ: Видавництво «КІМ», 2010. – 235с.